

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 6, 8, 10-12 and 16-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elsberry et al. (US Patent No. 5,603,703) in view of Thomas (US Patent No. 5,342,383). Elsberry discloses a system comprising a hollow rigid tube (Fig. 1, 16; col. 3, lines 18-19), including a proximal end (above element 12, near 14) and a distal end (near 20) and a lumen extending there between, wherein the hollow tube is shaped and sized to permit insertion into a lumen of a flexible tubular infusion catheter (element 18; col. 1, lines 9-13; col. 3, lines 56-59; col. 5, lines 6-18 all disclose that while the title of the invention is directed towards aspiration, the invention can be used for infusion, and thus is also an infusion catheter), and wherein the hollow tube is stiffer than the infusion catheter (col. 4, lines 29-31 disclose that a rigid stylet is used to add

rigidity to the stylet/catheter combination, which means that the stylet is inherently stiffer than the catheter, otherwise a rigid stylet wouldn't be needed) such that the hollow tube acts as a stylet for guiding the catheter through tissue to a target location.

Elsberry further discloses that the lumen of the hollow tube is filled with a fluid, and in which the proximal end of the hollow tube is configured to be closed to retain the fluid within the lumen of the hollow tube (col. 4, lines 56-66). Elsberry also discloses that a fluid reservoir is coupled to the proximal end of the hollow tube (col. 3, lines 42-44). Elsberry also discloses that the hollow tube and the fluid reservoir are sized to hold enough fluid to fill the lumen of the infusion catheter after withdrawal of the hollow tube from the lumen of the infusion catheter (col. 3, lines 56-66). Elsberry further discloses a flexible tubular infusion catheter (18) including a proximal end (near 12) and a distal end (near 20) and a lumen extending there between, the lumen of the infusion catheter sized and shaped to permit insertion of the hollow tube therein (see Fig. 1). Elsberry further discloses that the proximal end of the infusion catheter sealingly engages around the hollow tube when a portion of the hollow tube is located within the lumen of the infusion catheter (22 forms a seal around 16, alternatively see Fig. 4). Elsberry also discloses that the lumen of the catheter includes a diameter having at least two different values at different locations along the lumen of the catheter (Fig. 3 discloses that the catheter, here 26, has **two** different diameters, a larger diameter near the holes (28) and a smaller diameter near the tip). Elsberry also discloses means for temporarily sealing the proximal end (12) of the hollow tube to retain fluid within the hollow tube.

Elsberry further discloses a method comprising loading a hollow-tube stylet with fluid (col. 8, line 64); inserting the stylet into a lumen of a flexible infusion catheter to provide enough stiffening to the catheter to guide the catheter through living tissue toward a target (col. 8, lines 51-52 and lines 65-67); directing the stylet and the catheter through tissue to the target (col. 4, lines 30-37); and withdrawing the stylet from the catheter, in which the withdrawing includes releasing the fluid from the stylet into the lumen of the catheter to avoid air from occupying the lumen of the catheter upon withdrawal of the stylet (col. 9, lines 1-2 and claim 35). Elsberry further discloses temporarily closing a proximal end of the stylet, after loading the stylet with fluid, to assist in retaining the loaded fluid within the stylet (col. 4, lines 65-67). Elsberry further discloses opening the proximal end of the stylet after inserting the stylet into the lumen of the catheter and before withdrawing the stylet, to release fluid from the stylet into the lumen of the catheter and further including infusing a fluid agent through the catheter after withdrawing the stylet (claims 31 and 35).

Elsberry, however, does not disclose that the hollow rigid tube (stylet) has a remotely detectable locator positioned on the tube allowing the stylet to be tracked by a positioning system for proper positioning of the catheter within the patient's body. Thomas, however, discloses a stylet having a radiopaque material at the tip allowing the stylet to be tracked and viewed radiographically when positioned within the patient's body, thus allowing the physician to properly position the catheter which surrounds the stylet (abstract). The radiopaque material at the tip therefore is equivalent to the remotely detectable locator, as this is detected remotely (its position is detected and

viewed on a monitor by the physician, which is obviously remote from the interior of the body in which the stylet is located). The radiographic system used by the physician and medical personnel to view the stylet is equivalent to the positioning system and image guided surgical workstation claimed, as this is a system used/viewed in surgery for positioning the stylet and catheter. Please note that Applicant has broadly claimed the type of locator and positioning system and has not claimed any specifics such as is it detected magnetically, radiographically, via ultrasound, etc. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Elsberry with the remotely detectable radiopaque locator, as taught by Thomas, in order to provide a guiding and positioning system to properly and accurately position the catheter and stylet for treatment.

Claims 7 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elsberry in view of Thomas and further in view of Maginot et al. (US Patent No. 6,743,218). Elsberry in view of Thomas discloses the device substantially as claimed except for a clamp. Maginot, however, discloses a clamp (Fig. 3, 62 and 64) to be used at the proximal end of the catheter to prevent any fluid flow through the catheter system (col. 12, lines 12-18). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Elsberry in view of Thomas with the clamp as taught by Maginot in order to provide another mechanism in which stop the flow of fluid through the hollow tube.

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elsberry in view of Thomas and further in view of Hogan (US Patent No. 5,137,515). Elsberry in view of Thomas discloses the device substantially as claimed except for a cap and a plug at the end of the proximal tube. Hogan, however, discloses a cap (Fig. 1, 34) and plug (32) for the ends of a hollow tube (col. 3, lines 3-9). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Elsberry in view of Thomas with the cap and plug as taught by Hogan in order to provide mechanisms to seal the end of the hollow tube.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-4, 6-8, 10-25 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/

Examiner, Art Unit 3767

/Kevin C. Simmons/

Supervisory Patent Examiner, Art Unit 3767